Index of Exhibits

Exhibit A — Statements published by the NPA

Exhibit B — Morton Grove's letter to the NPA

08 C 1384

JUDGE BUCKLO
MAGISTRATE JUDGE MASON

EXHIBIT A

"The future will depend"on our wisdom not to replace one poison with another."

National Pediculosis Association®, Inc.

Signs and Symptoms of Lindane Exposure

Effects can be immediate or delayed. Onset of some symptoms may be subtle. May include one or combination of the following manifestations:

acute renal failure with azotemia,
ADD/ADHD
anxiety,
autism,
atonia,
agranulocytosis,
aplastic anemia,
anorexia,
apprehensive mental state,
behavior-mood disturbances,
bullae,
cancer,
cardiac arrhythmias,
clumsiness,
coma,
confusion,
conjunctivitis,
convulsions,
cough,
cyanosis,
death,
dermatitis,
diaphoresis,
diarrhea,
disorientation,
dizziness,
dyspnea,
emotional lability,
excitement,
excessive hair growth,
fast heartbeat,
fatigue,
fever,
giddiness,
grinding teeth,
headaches,
heart palpitations,
hematuria,

hyperirritability,
hypersensitivity,
incoordination,
kidney damage,
liver damage,
liver enlargement,
loss of appetite,
mania,
mental retardation,
muscle cramps, muscle spasms, muscle tremors,
nausea,
nervousness,
oliguria,
pallor,
paraesthesia,
paresis,
paresthesia,
porphyria,
proteinuria,
pulmonary edema,
restlessness,
respiratory failure,
seizures,
shaking,
sweating,
tachycardia,
tearing,
thirst,
trouble breathing,
trouble swallowing,
urticaria,
vertigo,
vomiting,
weakness,
wheezing,
elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes.

ACETONE:
dizziness,
light-headedness,
fainting,
headaches,
irritates eyes, nose, & throat,
unconsciousness
dermatitis,
liver & kidney damage

The signs and symptoms of exposure listed here are complied from all the data contained within the links of this site.

proceeds from our educational resources and sales of the LiceMeister Comb and LiceMeister Kit.

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Lindane Education And Research Network

Select a Destination

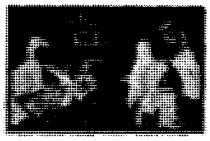
"The future will depend"on our wisdom not to replace one poison with another."

National Pediculosis Association®, Inc.

Lindane Regulatory Status

Illinois Bans Lindane

California Law



Regulatory Status by Country

Lindane Ban Campaign

World Ban

Back

Lindane Education And Research Network is a project of the National Pediculosis Association®

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Lindane Education And Research Network

"The future will depend"on our wisdom not to replace one poison with another."

National Pediculosis Association®, Inc.

Illinois Banned Lindane

Ban Lindane Now!
Lindane in Illinois
Articles & Resources
Discussion
Google Search
Lindane Petition

April 8, 2005

Full Text

Amends the Illinois Food, Drug, and Cosmetic Act. Provides that no person shall sell, deliver, offer for sale, hold for sale, give away, use, or prescribe any product used for the treatment of lice or scabies in human beings that contains the pesticide chemical lindane. Effective January 1, 2006.

http://www.ilga.gov/legislation/BillStatus.asp?DocTypeID=HB&DocNum=1362&GAID=8&SessionID=50&LegID=16128

Illinois: Progressive lobbyist Dan Johnson-Weinberger is spearheading an effort to pass state legislation banning lindane in Illinois. For more information contact Dan Johnson-Weinberger, midwestdemocracy@yahoo.com

- IL draft legislation
- IL PANAlert to State Representatives

Cancer Prevention Coalition
http://www.preventcancer.com/patients/children/lindane.htm

Google Illinois Lindane

Google News Search Lindane

http://www.panna.org/campaigns/lindaneState.html

Last modified:
05/03/2005 07:25 AM

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HeadLice.Org℠

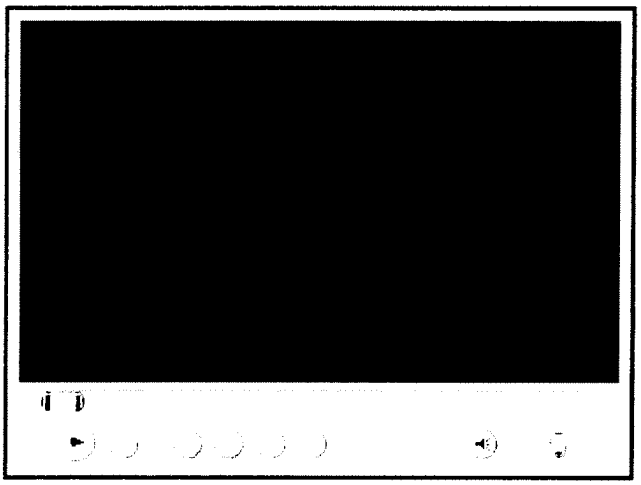
HeadLice.Org Hot Spots:
-- select a destination --

What *is* Lindane Anyway?

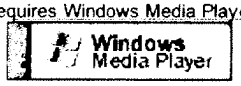
For starters it is consistently ranked among the top chemicals of concern by the Agency for Toxic Substances and Disease Registry. By any other name, lindane is the 99% pure gamma isomer of hexachlorocyclohexane. It was introduced as a pediculicide and scabicide in 1952 as Kwell by Reed and Carnrick. The Pharmaceutical Manufacturing Encyclopedia describes the manufacturing process of lindane as one in which ***chlorine gas*** is gradually passed into 660 part of ***benzene*** (a known carcinogen) until 890 parts of the gas has been absorbed. The mixture is stirred continuously and the temperature is maintained at 15 degrees C to 20 degrees C.

The supply of chlorine is then interrupted and the precipitated solid filtered off and dried. In weight, it is found to be equivalent of 900 parts. The mother liquid is then mixed with 330 parts of benzene and the mixture again treated with 890 part of chlorine in the manner described. After filtering the reaction mixture resulting from the second chlorination, the filtrate is again mixed with a smaller quantity of benzene and again chlorinated in a similar manner. In this way, a continuous process for the preparation of benzene hexachloride results.

This benzene hexachloride isomer mixture is then the raw material for lindane production.



Requires Windows Media Player



What does the Merck Index say about lindane?
According to the Centennial Edition of the Merck Index, poisoning with lindane may occur by ingestion, inhalation, or skin absorption; possible acute symptoms include headache, nausea, vomiting, diarrhea, tremors, weakness, convulsions, dyspnea, cyanosis circulatory collapse. The Merck Index states that "Lindane and other hexachlorocyclohexane isomers may reasonably be anticipated to be carcinogens."

Is there a connection between lindane and seizures?
The proconvulsant properties of repeated low doses of lindane were reported by Joy and

colleagues and it has been since this time that lindane has been used as a kindling agent for studying seizures in rats. M.E. Gilbert published her work with rats and lindane in, *Toxicology and Industrial Health*, Vol. 10, No. 4, 1994, *Neurotoxicology and Teratology*, Vol. 17, No 2 1995. Gilbert chose lindane for her studies because of its pharmacokinetic and pharmacodynamic properites well characterized in the rat. Those who think it is okay to keep prescribing lindane need to think again!

The United States is one of very few industrialized countries still using lindane in agriculture and for lice control. Sign this petition to U.S. Surgeon General, Richard H. Carmona, urging him to call for an immediate ban on lindane.

Visit Lindane.org for more information.

by Sean Delonas
New York Post - Jan. 18, 1995

Statement in Support of the Elimination of Lindane Use in North America

In June 2002, the environment ministers from Mexico, the United States, and Canada resolved to develop a North American Regional Action Plan (NARAP) for lindane through the Commission for Environmental Cooperation of North America. The Task Force on Lindane will gather in Montreal, Canada September 28-30, 2004 to draft the NARAP.

We direct the following statement, supported by the undersigned non-governmental organizations in Mexico, the U.S. and Canada, to the North American Task Force on Lindane and the Ministers of Environment and Health from each country.

Background
All three countries continue to allow pharmaceutical lindane use for pediculosis, lice, and scabies treatment. In Mexico, lindane is used mainly on livestock and as a seed insecticide for soil pest control. The 2002 U.S. Environmental Protection Agency (EPA) Re-registration Eligibility Decision allows lindane to be used as seed treatment for six grain crops: corn, wheat,

barley, oats, rye, and sorghum. All remaining agricultural uses of lindane in Canada will stop on December 31, 2004.

Findings

Lindane is a persistent, bioaccumulative, and toxic organochlorine insecticide. Lindane is banned by 17 countries. It is harmful to the environment and human health. Children are particularly vulnerable to the toxic effects of lindane. Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos. The International Agency for Research in Cancer (IARC) and the U.S. EPA classify lindane as a possible human carcinogen. Lindane is a potent neurotoxin, with symptoms from small exposures by ingestion or skin absorption ranging from nausea, dizziness, muscular weakness, tremors, and convulsions. Chronic effects include damage to the nervous system and liver disease. Worker exposures have resulted in blood disorders, headaches, convulsions, and disruption of the reproductive hormones of the endocrine system.

Lindane is highly persistent and travels long distances via atmospheric and oceanic currents. In fact, lindane, with its isomers, is the most abundant pesticide in Arctic air and water. Indigenous peoples of the north who rely on traditional diets of marine mammals and fish are particularly at risk from lindane exposure through foods. Lindane contaminates drinking water sources. The Los Angeles County Sanitation District estimates that one dose of a lindane treatment for head lice can pollute 6 million gallons of water to levels exceeding drinking water standards. This threat to clean drinking water, and the enormous costs of clean up, prompted California to ban lindane shampoos in 2002. Lindane is highly toxic to aquatic invertebrates, fish, and bees. It is a potential endocrine disruptor in birds, mammals, and possibly fish.

The undersigned organizations call upon the United States, Canada, and Mexico to specify the following actions in the in the North American Regional Action Plan for Lindane, applicable to each of the three countries:

- Rapid elimination of pharmaceutical, veterinary, and agricultural uses of lindane, with its use precluded given the availability of safer, affordable alternatives;
- Commitment to research and education programs that support alternatives to lindane, giving top priority to preventative and least-toxic alternatives;
- Delivery of education programs about the risks of lindane, emphasizing the protection of exposed populations of children, Indigenous peoples, and workers; and
- Active support for the expeditious inclusion of lindane among new substances added to the Stockholm (POPs) Convention for elimination as an Annex A substance.

Organizations Supporting of the Elimination of Lindane in North America		
Randy Virgin, Executive Director Alaska Center for the Environment Anchorage, Alaska U.S.A.	Pamela Miller, Executive Director Alaska Community Action on Toxics Anchorage, Alaska U.S.A.	Tom Atkinson, Executive Director Alaska Conservation Alliance/Alaska Conservation Voters Anchorage, Alaska U.S.A.
Andrea Carmen, Executive Director International Indian Treaty Council (IITC), an organization of Indigenous Peoples from North, Central, South America and the Pacific Palmer, Alaska, U.S.A.	Shawnee Hoover, Special Projects Director Beyond Pesticides/National Coalition Against the Misuse of Pesticides Washington D.C. U.S.A.	Gershon Cohen, Ph.D. Campaign to Safeguard America's Waters Earth Island Institute Haines, Alaska U.S.A. Karen Wristen, Executive Director Canadian Arctic Resources Committee Ottawa, Ontario, CANADA
Maite Cortés Colectivo Ecologista Jalisco	Mindahi Crescencio Bastida-Muñoz, President Consejo Mexicano para el Desarrollo Sustentable	Bob Shavelson, Executive Director Cook Inlet Keeper

MEXICO	MEXICO	Homer, Alaska U.S.A.
Erik Jansson, Executive Director Department of the Planet Earth Washington D.C. U.S.A.	Sharon Labchuk Earth Action Prince Edward Island, CANADA	Joe DiGangi, Ph.D. Environmental Health Fund Chicago, Illinois, U.S.A.
Bill Smedley, Executive Director GreenWatch Inc. Jersey Shore, Pennsylvania U.S.A.	Manna Jo Greene, Environmental Director Hudson River Sloop Clearwater, Inc. Poughkeepsie, New York U.S.A.	Patricia Diaz Huicholes y Plaguicidas MEXICO
Tom Goldtooth, Executive Director Indigenous Environmental Network Bemidji, Minnesota, U.S.A.	Angel Valencia, Coordinator Indigenous Network Against Pesticides Members in 8 countries	Jerry Troshynski, President Alaska Public Health Association Anchorage, Alaska U.S.A.
Jo Behm, M.S., R.N., Co-President Marin Golden Gate Learning Disabilities Association San Francisco, California U.S.A.	Gina Solomon, M.D., M.P.H. Natural Resources Defense Council Assistant Clinical Professor of Medicine, U.C. San Francisco San Francisco, California, U.S.A	Arthur Hussey, Executive Director Northern Alaska Environmental Center Fairbanks, Alaska U.S.A.
Kristin Schafer, Program Coordinator Pesticide Action Network North America San Francisco, California U.S.A.	Fernando Bejarano Red de Acción sobre Plaguicidas y Alternativas en Mexico (RAPAM) MEXICO	Clayton Thomas-Muller, Coordinator Resisting Environmental Destruction on Indigenous Lands (REDOIL) Network Vancouver, British Columbia CANADA
Ted Schettler, M.D., Science Director Science and Environmental Health Network Boston, Massachusetts U.S.A.	Irene Alexakos Sierra Club, Alaska Chapter Haines, Alaska U.S.A.	Kenyon Fields, Executive Director Sitka Conservation Society Sitka, Alaska U.S.A.
Phillip Dickey, Staff Scientist Washington Toxics Coalition Seattle, Washington U.S.A.	Aimee Boulanger, Executive Director Women's Voices for the Earth Missoula, Montana U.S.A.	Clifton Curtis, Director, Global Toxics Program World Wildlife Fund Washington D.C. U.S.A.

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The National Pediculosis Association,® Inc.
A Non-Profit Organization
Serving The Public Since 1983.

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Replacing one poison with another only continues to degrade the quality of all life.

Lindane Status

Laundering pesticide contaminated clothing

Common Name: Lindane
CAS Number: 58-89-9
DOT Number: NA 2761
Date: July, 1988

HAZARD SUMMARY

* Lindane can affect you when breathed in and by passing through your skin.
* Lindane should be handled as a CARCINOGEN WITH EXTREME CAUTION.
* Overexposure can cause irritability, restlessness, anxiety, poor appetite, and headache. Higher levels can also cause muscle twitching, convulsion (fits) and even death.
* It also may damage the developing fetus and reduce fertility in females.
* Repeated overexposure may cause liver damage.

IDENTIFICATION

Lindane is a colorless solid with a musty odor. It is an organochlorine insecticide.

REASON FOR CITATION

* Lindane is on the Hazardous Substance List because it is regulated by OSHA and cited by ACGIH, DOT, NTP, DEP and EPA.
* This chemical is on the Special Health Hazard Substance List because it is a CARCINOGEN.
* Definitions are attached.

HOW TO DETERMINE IF YOU ARE BEING EXPOSED

* Exposure to hazardous substances should be routinely evaluated. This may include collecting personal and area air samples. You can obtain copies of sampling results from your employer. You have a legal right to this information under OSHA 1910.20.
* If you think you are experiencing any work related health problems, see a doctor trained to recognize occupational diseases. Take this Fact Sheet with you.

WORKPLACE EXPOSURE LIMITS

OSHA: The legal airborne permissible exposure limit (PEL) is 0.5 mg/m3 averaged over an 8 hour workshift.
ACGIH: The recommended airborne exposure limit is 0.5 mg/m3 averaged over an 8 hour workshift.

* Lindane may be a CARCINOGEN in humans. There may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level.

WAYS OF REDUCING EXPOSURE

* Where possible, enclose operations and use local exhaust ventilation at the site of chemical release. If local exhaust ventilation or enclosure is not used, respirators should be worn.
* Wear protective work clothing.
* Wash thoroughly immediately after exposure to Lindane and at the end of the workshift.
* Post hazard and warning information in the work area. In addition, as part of an ongoing education and training effort, communicate all information on the health and safety hazards of Lindane to potentially exposed workers.

This Fact Sheet is a summary source of information of all potential and most severe health hazards that may result from exposure. Duration of exposure, concentration of the substance and other factors will affect your susceptibility to any of the potential effects described below.

HEALTH HAZARD INFORMATION

Acute Health Effects
The following acute (short term) health effects may occur immediately or shortly after exposure to Lindane:

* Overexposure by skin contact or breathing can cause restlessness, insomnia, anxiety, irritability, poor appetite and/or headache. Higher exposures can also cause muscle twitching, seizures, convulsions or "fits" and even death.

Chronic Health Effects
The following chronic (long term) health effects can occur at some time after exposure to Lindane and can last for months or years:

Cancer Hazard
* Lindane may be a CARCINOGEN in humans since it has been shown to cause liver, lung, endocrine glands and other types of cancer in animals.
* There is limited evidence that Lindane is associated with leukemia in humans.
* Many scientists believe there is no safe level of exposure to a carcinogen. Such substances may also have the potential for causing reproductive damage in humans.

Reproductive Hazard
* Lindane may damage the developing fetus.
* Lindane may decrease fertility in females.

Other Long Term Effects
* Repeated overexposure may damage the liver or cause damage to the nerves of the arms and legs, possibly with weakness and poor coordination.
* Exposure may also cause a serious drop in the blood cell count (aplastic anemia) or in the white blood cell count (agranulocytopenia).

MEDICAL TESTING

For those with frequent or potentially high exposure (half the TLV or greater, or significant skin contact), the following are recommended before beginning work and at regular times after that:

* Exam of the nervous system.

* Complete blood count (CBC).

If symptoms develop or overexposure is suspected, the following may also be useful:

* Blood test for Lindane (may not be accurate longer than 1 week after last exposure).
* Liver function tests.

Any evaluation should include a careful history of past and present symptoms with an exam. Medical tests that look for damage already done are not a substitute for controlling exposure.

Request copies of your medical testing. You have a legal right to this information under OSHA 1910.20.

WORKPLACE CONTROLS AND PRACTICES

Unless a less toxic chemical can be substituted for a hazardous substance, ENGINEERING CONTROLS are the most effective way of reducing exposure. The best protection is to enclose operations and/or provide local exhaust ventilation at the site of chemical release. Isolating operations can also reduce exposure. Using respirators or protective equipment is less effective than the controls mentioned above, but is sometimes necessary.

In evaluating the controls present in your workplace, consider: (1) how hazardous the substance is, (2) how much of the substance is released into the workplace and (3) whether harmful skin or eye contact could occur. Special controls should be in place for highly toxic chemicals or when significant skin, eye, or breathing exposures are possible.

In addition, the following controls are recommended:

* Where possible, automatically transfer Lindane from drums or other storage containers to process containers.
* Specific engineering controls are recommended for this chemical by NIOSH. Refer to the NIOSH criteria document: "Occupational exposure during the Manufacture and Formulation of Pesticides #78 174".

Good WORK PRACTICES can help to reduce hazardous exposures. The following work practices are recommended:

* Workers whose clothing has been contaminated by Lindane should change into clean clothing promptly.
* Do not take contaminated work clothes home. Family members could be exposed.
* Contaminated work clothes should be laundered by individuals who have been informed of the hazards of exposure to Lindane.
* If there is the possibility of skin exposure, emergency shower facilities should be provided.
* On skin contact with Lindane, immediately wash or shower to remove the chemical. At the end of the workshift, wash any areas of the body that may have contacted Lindane, whether or not known skin contact has occurred.
* Do not eat, smoke, or drink where Lindane is handled, processed, or stored, since the chemical can be swallowed. Wash hands carefully before eating or smoking.
* Use a vacuum or a wet method to reduce dust during cleanup. DO NOT DRY SWEEP.
* When vacuuming, a high efficiency particulate absolute (HEPA)

filter should be used, not a standard shop vacuum.

PERSONAL PROTECTIVE EQUIPMENT

WORKPLACE CONTROLS ARE BETTER THAN PERSONAL PROTECTIVE EQUIPMENT. However, for some jobs (such as outside work, confined space entry, jobs done only once in a while, or jobs done while workplace controls are being installed), personal protective equipment may be appropriate.

The following recommendations are only guidelines and may not apply to every situation.

Clothing
* Avoid skin contact with Lindane. Wear protective gloves and clothing. Safety equipment suppliers/manufacturers can provide recommendations on the most protective glove/clothing material for your operation.
* All protective clothing (suits, gloves, footwear, headgear) should be clean, available each day, and put on before work.

Eye Protection
* Wear dust proof goggles and face shield when working with powders or dust, unless full facepiece respiratory protection is worn.

Respiratory Protection
IMPROPER USE OF RESPIRATORS IS DANGEROUS. Such equipment should only be used if the employer has a written program that takes into account workplace conditions, requirements for worker training, respirator fit testing and medical exams, as described in OSHA 1910.134.

* Where the potential exists for exposures over 0.5 mg/m3, use a MSHA/NIOSH approved supplied air respirator with a full facepiece operated in the positive pressure mode or with a full facepiece, hood, or helmet in the continuous flow mode, or use a MSHA/NIOSH approved self contained breathing apparatus with a full facepiece operated in pressure demand or other positive pressure mode.
* Exposure to 1000 mg/m3 is immediately dangerous to life and health. If the possibility of exposures above 1000 mg/m3 exists, use a MSHA/NIOSH approved self contained breathing apparatus with a full facepiece operated in continuous flow or other positive pressure mode.

Common Name: Lindane
DOT Number: NA 2761
DOT Emergency Guide code: 55
CAS Number: 58-89-9

Hazard rating	NJ DOH	NFPA
FLAMMABILITY	Not Found	Not Rated
REACTIVITY	Not Found	Not Rated

POISONOUS GASES ARE PRODUCED IN FIRE

Hazard Rating Key: 0=minimal; 1=slight; 2=moderate; 3=serious; 4=severe

FIRE HAZARDS

* Use dry chemical, CO2, water spray, or foam extinguishers.
* POISONOUS GASES ARE PRODUCED IN FIRE, including Phosgene and Hydrogen Chloride.
* If employees are expected to fight fires, they must be trained and equipped as stated in OSHA 1910.156.

SPILLS AND EMERGENCIES

If Lindane is spilled, take the following steps:

* Restrict persons not wearing protective equipment from area of spill until cleanup is complete.
* Collect powdered material in the most convenient and safe manner and deposit in sealed containers.
* It may be necessary to contain and dispose of Lindane as a HAZARDOUS WASTE. Contact your state Environmental Program for specific recommendations.

==========
FOR LARGE SPILLS AND FIRES immediately call your fire department.
==========

HANDLING AND STORAGE

* Prior to working with Lindane you should be trained on its proper handling and storage.

* Lindane must be stored to avoid contact with STRONG ALKALIS and POWDERED METALS since violent reactions occur.
* Store in tightly closed containers in a cool, well ventilated area.

FIRST AID
POISON INFORMATION

Eye Contact
* Immediately flush with large amounts of water for at least 15 minutes, occasionally lifting upper and lower lids.

Skin Contact
* Quickly remove contaminated clothing. Immediately wash contaminated skin with large amounts of soap and water. Shampoo hair thoroughly if contaminated.

Breathing
* Remove the person from exposure.
* Begin rescue breathing if breathing has stopped and CPR if heart action has stopped.
* Transfer promptly to a medical facility.

PHYSICAL DATA

Water Solubility: Insoluble

OTHER COMMONLY USED NAMES

Chemical Name:
Cyclohexane, 1,2,3,4,5,6 Hexachloro , (1alpha, 2alpha, 3beta, 4alpha, 5alpha, 6beta)

Other Names and Formulations:
Benzene Hexachloride; Kwell R; gamma BHC Benhexachlor.

NEW JERSEY DEPARTMENT OF HEALTH
Right to Know Program
CN 368, Trenton, NJ 08625 0368

ECOLOGICAL INFORMATION

Lindane is an organochlorine insecticide which has been used against insects in a wide range of applications. It has been used to treat animals, buildings, humans for ectoparasites; clothes; water for mosquitoes; living plants, seeds, and soils. It may enter the environment from industrial discharges, insecticide applications, or spills.

ACUTE (SHORT-TERM) ECOLOGICAL EFFECTS

Acute toxic effects may include the death of animals, birds, or fish, and death or low growth rate in plants. Acute effects are seen two to four days after animals or plants come in contact with a toxic chemical substance.

Lindane has high acute toxicity to aquatic life and to birds. Insufficient data are available to evaluate or predict the short-term effects of Lindane to plants or land animals.

CHRONIC (LONG-TERM) ECOLOGICAL EFFECTS

Chronic toxic effects may include shortened lifespan, reproductive problems, lower fertility, and changes in appearance or behavior. Chronic effects can be seen long after first exposure(s) to a toxic chemical.

Lindane has high chronic toxicity to aquatic life. Insufficient data are available to evaluate or predict the long-term effects of Lindane to plants, birds or land animals.

WATER SOLUBILITY

Lindane is moderately soluble in water. Concentrations of between 1 to 1,000 milligrams will mix with a liter of water.

DISTRIBUTION AND PERSISTENCE IN THE ENVIRONMENT

Lindane is moderately persistent in water, with a half-life of between 20 to 200 days. The half-life of a pollutant is the amount of time it takes for one-half of the chemical to be degraded. About 52.3% of Lindane will eventually end up in water; about 23.4% will end up in terrestrial soil; about 22% will end up in aquatic sediments; and about 2.3% will end up in air.

BIOACCUMULATION IN AQUATIC ORGANISMS

Some substances increase in concentration, or bioaccumulate, in living organisms as they breathe contaminated air, drink contaminated water, or eat contaminated food. These chemicals can become concentrated in the tissues and internal organs of animals and humans.

The concentration of Lindane found in fish tissues is expected to be somewhat higher than the average concentration of Lindane in the

water from which the fish was taken.
SUPPORT DOCUMENT: AQUIRE Database, ERL-Duluth, U.S. EPA.
http://chppm-www.apgea.army.mil/ento/facts/lindane.htm

LINDANE STATUS

We have received many inquiries recently on the status of the 1% lindane. As a result, we are printing the message which was sent out regarding the turn-in of the lindane stocks.

PRIORITY/ROUTINE
P R 141800Z APR 94
FM DGSC RICHMOND VA//STAC//QED//

UNCLAS
SUBJECT: AFPMB NOTICE ON INSECTICIDE, LINDANE DUSTS

1. Reference: Armed Forces Pest Management Board/AFPMB/letter, 25 March 1994/Not to all/.

2. Addresses are responsible for dissemination of this message to all lateral and subordinate units, maintenance activities, elements or foreign users affected or concerned. Include DGSC, Richmond, VA/STAC as info addressee on all retransmitted messages. This is a coordinated DGSC-S/Q message.

3. All service inventories of NSN 6840-00-242-4217, 1 percent lindane in 2 oz containers shall be turned in to the local DRMO for disposal. NSN was cancelled 1 January 1993. No DOD requirements exist. DGSC does not have this NSN in our inventory.

4. All DLA and service inventories of NSN 6840-00-242-4219, 1 percent lindane in 25 lb. drum also shall be turned in to the local DRMO for disposal. Action has been initiated to cancel NSN without replacement.

5. The rationale for these actions is threefold. First, DOD is changing the treatment procedures for mass delousing: The indiscriminate application of lindane, without first determining whether individuals are infested with lice, is not a sound pest management practice. Second, although lindane is currently registered by the environmental protection agency, it is a very persistent pesticide in the environment and it is categorized as a "B2" carcinogen/probable carcinogen based on animal studies. Finally, discontinuing used of lindane is consistent with pesticide risk reduction goals established by the Defense Environmental Security Council.

6. These actions are mandatory. DOD Directive 4150.7 and DOD Directive 6050-10 provides the AFPMB the authority for this turn in and disposal.

7. If you have questions concerning these actions, please contact Mr. Clifford Myers, DGSC-STAC, Chemist, DSN 695-3995 or 804-279-3995 or LtCol Bob McKenna at DSN 291-5191 or 301-427-5191.

http://chppm-www.apgea.army.mil/ento/bulsep94.htm

LAUNDERING PESTICIDE CONTAMINATED CLOTHING

The following information was printed in the *Pesticide Control Report*, published by the New Jersey Department of Environmental Protection and Energy. We think the information is worth repeating here in our Bulletin.

Pesticides are necessary tools in pest management but, like any other tool, they can be dangerous when mishandled or when accidents occur. Drift, accidental spills, or carelessness can cause pesticide contact with the user or his/her clothing. This clothing is then considered contaminated.

If pesticides get on your clothing, change clothes as soon as possible. Don't wait until the end of the day or until you've finished the job. If you continue to wear pesticide-contaminated clothing, the pesticide residue could be absorbed through your skin into your bloodstream, where it could cause serious health problems.

When you handle pesticide-contaminated clothing, always wear unlined waterproof gloves. Also, thoroughly clean washers after laundering contaminated clothing. This means that after every load of pes- ticide-contaminated clothing, run the machine through a complete cycle with hot water and detergent only. This simple step requires a little extra time, but studies show that it will help to prevent contaminating future wash loads.

Before bringing contaminated clothing into the shop, decide whether you can launder it thoroughly or if you should discard the clothing. Discard clothing saturated with highly toxic, undiluted pesticide formulations, such as emulsifiable concentrates. Dispose of the clothing by placing it in a plastic bag, closing the bag tightly, and disposing of it in an approved sanitary landfill.

Never take pesticide contaminated clothing home to be laundered in the family washing machine. Launder **ONLY** clothing contaminated with water-soluble low-toxicity pesticides. Discard contaminated leather items, such as watchbands, gloves, and boots. You cannot decontaminate leather items. When these items are worn again and become wet, the pesticide residue could become active again and could cause a rash or sores.

Never handle pesticide-contaminated clothing with your bare hands. To avoid dermal exposure, always wear unlined waterproof gloves. Wash the gloves off thoroughly before removing them and use them for this purpose only. Test gloves for leaks by filling them with water and gently squeezing. Discard gloves as soon as they develop a leak.

On a daily basis, launder clothing worn during pesticide applications, Pesticide residues in clothing can build up and become more difficult to remove.

If you must store contaminated clothing before laundering, hang them in an area not used by you or your co-workers, and where air movement will help dissipate or remove some of the pesticide.

Because pesticide residues could be transferred to other clothing in the wash load, always launder contaminated clothes separately. This will help prevent contaminating clothing worn by other workers.

Research at North Dakota State University shows that prerinsing is a very important step. It not only reduces the amount of pesticide in contaminated clothing before laundering, but it also minimizes contamination of laundry equipment, which could then contaminate clothing in future wash loads.

Empty pockets and cuffs of any pesticide granules outdoors, and discard them safely. In a bucket or pail, prerinse contaminated clothing in hot or warm water at least twice. Because pesticide formulations usually contain some detergent, it is not necessary to add detergents when prerinsing. Dispose of prerinse water as a pesticide-related waste.

Launder only a few (three or four) contaminated garments at a time. Use a full water level to thoroughly flush the pesticide from the fabric. This also decreases the possibility of redepositing pesticide residue on fabric.

Wash together only garments contaminated with the same pesticide. Hot (140 F) water is most effective in removing pesticide residues from clothing. Cold water is least effective.

Use a normal 12-minute wash cycle. Select detergents according to the type of pesticide that contaminated the clothing. Research has shown that heavy-duty detergents, such as Era and Wisk , are more effective than other detergents in removing emulsifiable concentrate pesticide formulations. Emulsifiable concentrate formulations are oil-based and heavy- duty liquid detergents are known for their oil-removing ability. Research shows that granular detergents such as Tide , Oxydol , and Cheer, are effective in removing water-soluble pesticides. If it is not possible to determine the pesticide formulation, use a heavy-duty detergent.

Results to date show that neither bleach nor ammonia aid in the removal of pesticide residues. You may wish to use them to remove other types of soil or stains, but never mix them together. In combination, they react to form a fatal chlorine gas.

For more effective removal of pesticide residue, repeat the wash cycle several times.

Line dry laundered garments outdoors. This eliminates the possibility of pesticide residue collecting in the dryer where it could contaminate clothes in future loads. Sunlight and air movement help to decontaminate any pesticide residue not removed during laundering.

If you must use a clothes dryer, wipe the dryer with a damp cloth after each load, and then discard the cloth.

Laundering pesticide-contaminated clothing correctly must be an important activity of any pest management operation. Now would be a good time to evaluate how your pest management activity launders clothing contaminated with pesticides.

http://chppm-www.apgea.army.mil/ento/bulsep94.htm

HeadLice.Org[SM]

HeadLice.Org Hot Spots:
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The NPA's efforts to eliminate lindane get a huge boost

NPA Press Release
11/01/01

The National Pediculosis Association (NPA) and Los Angeles County Sanitation District's (LACSD) efforts to eliminate lindane got a huge boost from an impressive list of other organizations during the time for public comment on the EPA's Preliminary Risk Assessment for Lindane.

Lindane, first used as a smoke bomb during WWI, is an endocrine disrupting, bio-accumulative and toxic chemical. It is a known health risk to humans, especially children, with potential adverse effects ranging from learning disabilities, to birth defects, to breast cancer, to leukemia, to seizures, to death. Lindane is an unnecessary risk to all forms of life and for this reason has been banned in pharmaceutical products the state of California. The goal is not just to eliminate lindane, but also to ensure it is not replaced with yet another poison.

Advising the EPA in their risk assessment, The Natural Resources Defense Council (NRDC) Senior Scientist Gina M. Solomon, M.D., M.P.H., submitted comments on behalf of NRDC, Commonweal, Institute for Agriculture and Trade Policy, Northwest Coalition for Alternatives to Pesticides, Physicians for Social Responsibility-Los Angeles & San Francisco Bay Area, and Washington Toxics Coalition. Their joint statement strongly advises the EPA to correct the major flaws in their lindane risk assessment. Dr. Solomon summarizes, "On reviewing the literature on lindane's persistence, bioaccumulation in the environment and in human tissues, and toxicity, we do not believe that this chemical can safely be registered for use in the United States."

Also participating in this effort were The Alaska Community Actions on Toxics, Breast Cancer Action, Environmental Health Coalition, KidSource, Northwest Coalition for Alternatives to Pesticides, The Sierra Club, Tri-TAC, and the World Wildlife Fund.

The NPA and LACSD received the most prestigious pollution prevention award in the country for 2001. Senator Diane Feinstein commended the NPA and LACSD stating, "Your commitment to reducing lindane at the source represents a unique and innovative approach to protecting the environment. Lindane is a persistent bio-accumulative and toxic chemical that is dangerous to the environment, harmful to human health and threatening to the food chain. I was appalled to learn that lindane is still used to treat head lice."

The links below will take you to some examples of these letters.

Letter submitted by The National Resources Defense Council
2nd Letter submitted by The National Resources Defense Council
Letter submitted by The NPA
Letter submitted by The World Wildlife Fund

Letter submitted by The Tri-TAC
Letter submitted by The LACSD
2nd Letter submitted by The LACSD
Letter submitted by The NYS Attorney General

Keep up the great work! The NPA & LACSD want to commend these organizations for their action and acknowledgement of the broad reaching effects lindane has on the public health and the environment:
Alaska Community Actions on Toxics
Breast Cancer Action
Commonweal
Environmental Health Coalition
Environmental Protection Agency - Region 9
Institute for Agricultural and Trade Policy
KidSource
National Resources Defense Council
The New York State Office of Attorney General
Northwest Coalition for Alternatives to Pesticides
Pesticide Action Network
Physicians for Social Responsibilty - Los Angeles
Physicians for Social Responsibilty - San Francisco Bay Area
The Sierra Club
Tri-TAC
The Washington Toxics Coalition
World Wildlife Fund

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HeadLice.Org℠

HeadLice.Org Hot Spots:
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No matter what you do...

Be Sure You Provide a Non-Chemical Choice For Your Children, Their Families, Your Staff and Yourself!

Why? Because children of any age or size are vulnerable to the harmful effects of pesticides. They also often have pregnant or nursing mothers who should never be exposed to chemical treatments either by applying them to themselves or to others.

Why? Because too many people unfortunately overuse chemical agents out of fear and frustration without adequate warning of the risks to themselves and the environment.

Why? Because each of us has our own unique vulnerabilities. Pesticide products can accumulate in the human body and they are not necessarily washed away at the end of the treatment, as people would like to think.

Why? Because the overuse of lice products can predispose a person to adverse reactions with even one additional chemical exposure.

Why? Because it's not worth taking unnecessary risks when the bottom line will always be the manual removal of lice and nits.

Why? Because none of the available chemical treatments are 100% effective and too many people are told to seek prescriptions after other treatments fail. Prescriptions become the most potentially harmful treatment of them all!

Why? Because pesticides pose a risk to all children, and none are more at risk than the growing number treated for illnesses and/or on medication.

Why? Because everyone needs a non-chemical way to screen and detect head lice early and remove them safely and effectively.

Why? "Cuz if you don't get 'em out, you've still got 'em!™"

"Because it's not about lice, it's about kids™"

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Resistant Lice?

The NPA receives calls everyday from parents and health professionals reporting product treatment failure ... reports of folks using "everything on the drug store shelf," only to continue finding adult-sized crawling lice.

Unfortunately, frustrated parents have responded to persistent infestations by repeatedly using treatment products, or by resorting to dangerous alternatives. There are many elements that can play a role in treatment failure. While there is more than sufficient reason to seriously consider insect resistance, we must also acknowledge other possible contributing factors such as failure to follow product treatment instructions, failure to remove all nits, and false hope generated by product marketing promises.

Until the treatment failure crisis is fully addressed by the scientific and medical community as well as the product manufacturers, the NPA is offering the following suggestions for those who use a lice treatment product and experience treatment failure:

- If you continue to be infested with live lice after treatment, discontinue use of the products and don't use other products in the hope of killing the lice. Remember, these products are not mere shampoos, cremes or lotions, they are pesticides.
- Never resort to dangerous remedies such as lindane, kerosene, or pet shampoos.
- Manual removal is crucial. Beyond snipping or pulling out the nits, you should also be screening for and removing live lice. Having at least two people check an infested person is important as one person cannot see the entire scalp. Lice move quickly and shy away from light when you are checking.
- Don't spend hours on end cleaning your environment. Head lice need human blood to survive. Vacuum surface areas only. Save your time and energy for what will benefit you most, delousing the individual. NEVER USE A LICE SPRAY!
- When screening for lice with a nit-removal comb, it may be helpful to dip it into water and clean it before going to the next section of hair.
- Equip yourself and your helpers with a magnifying glass, tweezers, safety scissors, and a nit-removal comb.
- If you are experiencing treatment failure, please report it to the NPA's Registry by clicking here.

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The LiceMeister Comb

Gold Standard

SEARCH

for stores selling the LiceMeister (US & Canada)

How to use
watch video

Catalog

Critter Cards

LiceMeister Kit

The LiceMeister Comb

The only comb endorsed by the National Pediculosis Association.® The "Gold Standard" medical device packaged with combing instructions, a convenient cleaning tool

And bonus:

NPA's Critter Card to show you what to look for and know how to see the difference between lice eggs (nits) and normal hair debris.

What Makes the LiceMeister the Best Lice and Nit Removal Comb? Find Out

ORDER NOW

Order Online:

NPA Online Catalog

also available at:
Healthgiant.com
Shopinprivate.com
CVS.com

Call the NPA Order Line:

1-866-323-5465 ext 8065

International Orders:

Canada
Korea
UK
Other

The Fight Against Head Lice

When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school, lice and nit free!

The NPA is a non-profit organization. Proceeds from the LiceMeister comb help support the NPA's programs of education, prevention and research.

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Pharmacist's Guide to Controlling Head Lice

With the exceptions of the common cold, head lice affect more school-aged children than all other communicable diseases combined. Studies show that the public wants to receive more advice from their pharmacist, and the trend in pharmacy practice is to provide more consultative services. All summed up, this means that pharmacists will, and should, assume a leadership role in the community effort to develop a sound and standardized approach to controlling head lice.

There is a lot of misinformation on this disease and its control. This is especially true on the Internet. There are many products being marketed as safe and natural alternatives yet labeled with pesticidal claims. The majority of these products have not been reviewed or approved by the Food and Drug Administration for human safety, manufacturing practices, or efficacy.

Encourage everyone to get the facts and CHECK A HEAD.™

1. Determine if the patient has head lice: If there is not a diagnosis from a qualified health professional or knowledgeable parent, you may need to advise on how to identify an infestation.

A. When inspecting the scalp and hair, look for nits – tiny yellowish-white oval eggs firmly attached at an angle to the side of the hair shaft. Unlike what most pharmacists were taught in school, the nits a quarter inch from the scalp or further are not necessarily dead. Viable eggs can be found anywhere on the hair.

B. An infestation is often detected by seeing nits rather than by finding head lice. Head lice, which shy away from the light and move quickly, may also be seen. They are the size of a sesame seed; are transparent as nymphs but with blood meals take on a reddish brown to black color.

C. Using an effective screening device, such as the NPA's LiceMeister® comb, go through each section of hair from the scalp to the end of the hair. (Head lice can also be found in the eyebrows and eyelashes. Children should be examined by their physician in this situation.) Pesticides should not be used on or near the eyes.

D. Be sure that patients do not confuse nits with hair debris such as desquamated epithelial cells (DEC plugs), which are bright white and irregularly shaped clumps of dandruff stuck to the hair shaft, or haircasts (elongated segments of dandruff that encircle the hair shaft). Both can occur in patients who have been over-treated with pesticides. Such debris can cause diagnostic confusion.

E. Nits may be found throughout the hair, but are often found at the nape of the neck, behind the ears, and at the crown.

F. Remind parents that routine screening and early detection is the best and only

prevention. Pesticides should not be used to prevent head lice.

G. Be mindful that some parents will assume that they or their children are infested whenever they hear that there is an outbreak. This is okay if it prompts them to screen... but not if it causes them to use pesticides unnecessarily.

2. Alert those who are at greatest risk from the use of pesticides. These issues also apply to the person administering the treatment. Some of the factors impinging on the treatment choice include:

A. The health/age/size of the child.

B. Whether the person applying or using the product is pregnant or nursing.

C. Whether there are several infested family members to be treated by one parent.

D. Individuals who have had repeated earlier pesticidal treatments.

E. Patients on medication or with pre-existing medical conditions such as allergies, asthma, epilepsy, cancer, or with open wounds on the hands, scalp or neck.

3. Product Recommendations:

A. Based on increasing reports of head lice resistance on a national level, the NPA advises parents to discontinue the use of head lice pesticides at the earliest sign of treatment failure. MANUAL REMOVAL IS THE BEST OPTION WHENEVER POSSIBLE AND ESPECIALLY WHEN TREATMENT PRODUCTS HAVE FAILED.

B. Head lice treatments should be used over a sink, as opposed to a bath or shower as it will minimize the exposure of pesticides to the body. Caution against allowing these products to get near the eyes.

C. Warn against the use of head lice sprays. Using head lice sprays on bedding, furniture, and carpets is unwarranted, has no scientific basis, and may pose personal and environmental hazards.

D. Do not recommend products containing lindane. The Food and Drug Administration (FDA) regards it as potentially more toxic than all other pediculicidal choices and no more effective. None of the commercially available products will kill 100% of the nits.

E. Provide educational materials about head lice control near the head lice products in the pharmacy, and encourage affected persons to discuss their experience with you.

F. The current endemic nature of head lice among children challenges the traditional management concept that the lack of efficacy in pediculicides can be countered by retreating children in 7-10 days later to kill the newly hatched lice. The 7-10 day time span is nebulous. More importantly, such a measure does not take into account the opportunities to become reinfested from another child in the interim.

4. Additional Control Measures for Patients

A. Have parents screen as part of personal hygiene – routinely just as they brush their

teeth. Early detection is key and is consistent with traditional communicable disease control methods.

B. Have parents machine wash all potentially exposed clothes, sheets, etc. in hot water, and dry them in a hot dryer.

C. Any item that can't be washed or dry-cleaned can be vacuumed. Recommend vacuuming as the safest and most effective alternative to spraying.

D. Some professionals have suggested "bagging" items in plastic bags. Discourage bagging and encourage vacuuming. Having head lice can be traumatic, especially for children. Often it's their favorite stuffed animal, or blanket that gets bagged, just when they need it most. Parents should know to save their energy for that which benefits them the most: attention to the scalp and hair for early detection along with complete lice and nit removal.

E. Do not recommend retreatment based on the patient's scalp being "itchy." Remember that prior treatment itself can cause the scalp to itch and this symptom does not validate an infestation.

F. Inquire about daily screening and thorough nit removal. Remind the patient that an ongoing infestation is predictable without these measures.

5. Prevent new outbreaks.

A. Encourage parents to notify their child's school, camp, childcare provider, and neighborhood parents regarding possible outbreaks. Parents should check for head lice on a regular basis. Remember that head lice affect all social groups. Reporting should be encouraged.

B. Advise AGAINST treating anybody who is not infested. Do not recommend prophylactic treatment.

Public Health Aspects: Minimize community outbreaks by taking a leadership role in lice prevention in your community.

1. Minimize Community Outbreaks

A. Inform your community that you want to be part of a community approach – that you are available for educational information as well as advice about treatment and head lice management.

B. You may choose to provide in-service training for local teachers, YMCA staff, camp directors, childcare personnel, etc.

C. Support the important step of reporting outbreaks, treatment failures, and adverse reactions to the NPA's National Reporting Registry, local health departments, and school officials. Remember that early reporting can mobilize communities to do preventive screening.

D. Encourage routine screening, early detection, and complete removal of both lice and nits.

2. Take a leadership role in lice prevention in your community.

A. Teach others how to minimize outbreaks. Because most head lice information comes from product advertising, you should look to the National Pediculosis Association® for impartial resources and materials.

B. Encourage everyone to join the NPA's Back-To-School "National Pediculosis Prevention Month" activities that continue throughout the year.

3. Advise others to exercise caution in selecting and using products for treatment. Overuse of anti-lice pesticides has caused insect resistance similar to the current situation with some bacteria and antibiotics.

4. Update physicians about possible new treatments and issues related to Pediculosis.
Head lice are often perceived as "unglamorous" and unworthy of serious attention. As a result, there is conflicting information and no nationally standardized approach. Encourage everyone to get the facts and CHECK A HEAD.™

GUIDE DEVELOPED BY:
National Pediculosis Association
50 Kearney Road
Needham, MA 02494
(781) 449-NITS
www.headlice.org

in cooperation with Pharmacist's Letter®

Click here for printable versions of this and other NPA publications

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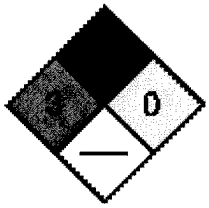
Lindane Education And Research Network

Replacing one poison with another only continues to degrade the quality of all life.

Lindane



Lindane is used as an insecticide on fruit and vegetable crops, for seed treatment, in forestry, and for animal treatment. It is no longer produced in the United States and aerial application of the chemical is prohibited; however, it is still formulated in this country. Lindane is also used topically for the treatment of head and body lice and scabies; it is available in 1% preparations as a lotion, cream, or shampoo.

Lindane is quite toxic to humans. The acute (short-term) effects of lindane through inhalation exposure in humans consist of irritation of the nose and throat and effects on the blood and skin. Chronic (long-term) exposure to lindane by inhalation in humans has been associated with effects on the liver, blood, and nervous, cardiovascular, and immune systems. The Reference Concentration (RfC) for lindane is under review by the U.S. Environmental Protection Agency (EPA).

Limited information is available on the reproductive or developmental effects of lindane in humans. Animal studies indicate that lindane causes reproductive effects, such as decreased sperm count, via oral exposure, while developmental effects, including birth defects, have not been noted. No studies are available on the carcinogenic effects of lindane in humans or animals via inhalation exposure. Oral animal studies have shown lindane to be a liver carcinogen. EPA has classified lindane as a possible human carcinogen of low to medium carcinogenic hazard.

The most probable route of lindane exposure in humans is oral ingestion of food containing the insecticide. Lindane may be released to the air during its formulation, from wind erosion of contaminated soil, or from release from hazardous waste sites. Lindane has been detected in groundwater and surface water samples collected near hazardous waste sites; however, the chemical has only very rarely been detected in drinking water supplies. Lindane has been listed as a pollutant of concern to EPA's Great Waters Program due to its persistence in the environment, potential to bioaccumulate, and toxicity to humans and the environment.

Lindane can be measured in the blood, urine, and semen of exposed individuals by gas chromatography.

CEHS website:
http://www.envtox.ucdavis.edu/CEHS/Index.htm

Back

EXHIBIT B

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January 22, 2007

VIA FEDERAL EXPRESS
Deborah Z. Altschuler
President
The National Pediculosis Association, Inc.
50 Kearney Road
Needham, MA 02494

Re: Lindane

Dear Ms. Altschuler:

I write on behalf of our client Morton Grove Pharmaceuticals, Inc. ("Morton Grove") in relation to the National Pediculosis Association, Inc.'s ("NPA") publication of false advertising claims regarding two of Morton Grove's products, Lindane Lotion and Lindane Shampoo (collectively "Lindane"). Lindane, as you know, is a competitor with the LiceMeister® comb in the marketplace of products for the treatment of lice and scabies.

Morton Grove has learned that the NPA has published false advertising claims and defamatory comments to healthcare providers, institutions, associations, and patients through a variety of means, including www.headlice.org. Morton Grove is requesting that you immediately cease making such claims and statements. These claims and statements have caused and will continue to cause others to believe that Lindane is not a safe and effective product when used as directed, and does not alleviate affects of the diseases for which it is FDA-approved. The NPA's false advertising claims and false and defamatory statements have caused and will continue to cause Morton Grove to incur substantial damages.

As the sole United States manufacturer of Lindane, Morton Grove wholly stands behind the safety of its products and the health benefits they provide. The NPA has done a great disservice by widely disseminating such claims and statements to healthcare providers and patients about Lindane.

As a mechanism for profiting from additional sales of the LiceMeister® comb and in an effort to decrease Lindane sales, the NPA has published numerous statements that are false,

misleading, and defamatory. These statements violate the Lanham Act, 15 U.S.C. § 1125(a), and constitute defamation.

As you know, Lindane is regulated and approved by the FDA as prescription medications for the "second-line" treatment for scabies, pubic lice and head lice, which are all highly contagious health conditions – some of which are sexually transmitted. These diseases affect adolescents, adults, and children; cause significant morbidity; and impact millions worldwide. These products have been used successfully in clinical practice for more than 50 years.

It is a matter of public record that both the FDA and the EPA, after repeated and exhaustive reviews by medical and scientific subject matter experts, have concluded that currently approved uses of Lindane medications do not pose a significant risk to public health or safety. Consistently, the FDA has maintained that the benefits of Lindane medications, when used appropriately, outweigh potential risks, a factor in the use of all medications. Petitions to ban their use have all been dismissed and determined to be without merit, including those submitted by the NPA. The FDA continues to support the use and manufacture of Lindane as a second-line therapy for patients who have no other options. Additionally, the Centers for Disease Control and Prevention (CDC), which helps to set practice standards for the medical community, include Lindane in its *Sexually Transmitted Disease Treatment Guidelines* for the treatment of scabies and pubic lice, consistent with the FDA-approved prescription labeling.

According to the FDA's Division of Drug Marketing and Advertising, advertisements, such as those contained on the NPA's website, may not use comparative test data or reference published reports, unless the representations made in the advertisement are supported by substantial evidence derived from adequate and well-controlled studies. We do not believe the NPA advertising claims discussed herein comport with this standard.

It is well established that the FDA has the jurisdictional authority over the decision of whether a particular pharmaceutical product should or should not be on the market. Under applicable law, the "FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective" based upon "a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance." (Department of Health and Human Services, Food and Drug Administration, [Docket No. 2000N-1269] (formerly Docket No. 00N-1269) January 24, 2006.)

We are hereby demanding a retraction of all such statements by the NPA. We are prepared to allow a reasonable time for the NPA to prepare and distribute a retraction. The requested retraction must be circulated in the same scope and manner (specifically, your website,

e-mail, correspondence, fact sheets, or other written and oral communications) as other publications that contained your false statements. We are prepared to allow up to two weeks, through February 5, 2007, for the NPA to prepare and issue this retraction. We would request a written confirmation of the persons to whom you will direct this retraction and a copy of the retraction.

In the event that the NPA ignores this request and/or refuse to issue a retraction, please understand that Morton Grove is prepared to take legal appropriate action.

This letter will also serve to document the false advertising claims and statements that Morton Grove currently believes the NPA has made which are to be the subject of the requested retraction.

The false statements the NPA made include, but are not limited to, the following:

False Statement: "symptoms" from "exposure" to Lindane include: "acute renal failure with azotemia, ADD/ADHD[,] anxiety, autism, atonia, agranulocytosis, aplastic anemia, anorexia, apprehensive mental state, behavior-mood disturbances, bullae, cancer, cardiac arrhythmias, clumsiness, coma, confusion, conjunctivitis, convulsions, cough, cyanosis, death, dermatitis, diaphoresis, diarrhea, disorientation, dizziness, dyspnea, emotional liability, excitement, excessive hair growth, fast heartbeat, fatigue, fever, giddiness, grinding teeth, headaches, heart palpitations, hematuria, hyperirritability, hypersensitivity, incoordination, kidney damage, liver damage, liver enlargement, loss of appetite, mania, mental retardation, muscle cramps, muscle spasms, muscle tremors, nausea, nervousness, oliguria, pallor, paraesthesia, paresis, paresthesia, porphyria, proteinuria, pulmonary edema, restlessness, respiratory failure, seizures, shaking, sweating, tachycardia, tearing, thirst, trouble breathing, trouble swallowing, urticaria, vertigo, vomiting, weakness, wheezing, elevated LDH, GOT, GPT, alkaline phosphatase, ALT, AST enzymes."

Facts: This claim is false, misleading and inaccurate, and it falsely portrays the safety profile of Lindane. The vast majority of these alleged side-effects are not listed in the FDA-approved prescription label for Lindane, and they also do not reflect the events reported to the FDA through their Adverse Event Reporting System Database (1951 – 2003) or to Morton Grove since they acquired the medications in 1995. You have not made any effort to support this highly misleading and injuring claim.

False Statement: "Illinois Bans Lindane"; "Illinois banned Lindane"

Facts: The State of Illinois has never banned Lindane.

False Statement: Lindane is "sold or prescribed without adequate warnings or guidance on use. It is applied to the scalp and overuse is encouraged."

Facts: Quite the opposite, Morton Grove and the FDA have taken significant steps to discourage overuse, including (1) adding a boxed warning, (2) issuing a public health advisory, (3) repackaging the product in small, single-use bottles, and (4) distributing legally required patient guides with every Lindane prescription.

False Statement: "When these [first-line] treatments fail, the guidelines unfortunately recommend the prescription pesticides malathion and Lindane. There are health risks inherent with the use of pesticides on children and these risks increase dramatically when you follow one chemical treatment with another."

Facts: There is no credible scientific evidence to support the statement that "risks increase dramatically when you follow one chemical treatment with another." In fact, the Centers for Disease Control and Prevention and the American Academy of Pediatrics recommend the practice of using over-the-counter products first and then using Lindane if those are not effective. This recommendation, which is also supported by the FDA, is implicit to the use of "second-line" medications like Lindane Lotion and Lindane Shampoo,

False Statement: "[T]he main source of lindane in sewers is from the treatment of head lice and scabies and that a single treatment of lindane pollutes 6 million gallons of drinking water."

Facts: This statement is false. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had Lindane levels that were above conservative levels considered safe. (United States EPA Review of Drinking Water Standards, 2003.) The United State Geologic Survey also conducted large-scale contaminant testing of 139 streams near large cities and farms across 30 states and found that 93.9% of the samples tested negative for Lindane. Of the 5.9% of samples that tested positive, all were well below levels considered unsafe. (Kolpin DW, et al. 2002.)

The EPA sets Maximum Containment Levels (MCL) for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for Lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of Lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping Lindane levels below the more conservative 1991 MCL of 0.2 ppb. (United States EPA Review of Drinking Water Standards, 2003.)

To strike home how preposterous the above "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., D.A.B.T., A.T.S., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" analysis that if 100% of prescribed Lindane shampoo and lotion sold in the Albany, New York area (based upon the proportional number of New York 2004 prescriptions) was instead poured directly into Albany's drinking water supply, Lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the level considered safe in 2003.

The EPA has similarly concluded in its most recent scientific evaluations of Lindane, as previously stated, that, "[T]he Agency does not have risk concerns for concentrations of Lindane in surface water used as a source of drinking water from consumer use for both lice and scabies." (United States EPA Lindane RED, 2002.)

False Statement: "When used for early detection and manual removal, the LiceMeister comb is the realistic and practical alternative to unnecessary and potentially harmful pesticides. The LiceMeister is the safe and cost effective way to win the war against head lice and keep the kids in school safe, lice and nit free."

Facts: While appropriate for patients who are not candidates for pediculicidal therapy, the scientific evidence for the effectiveness of combing in controlling lice infestations is generally considered to be lacking. In a rigorous head-to-head clinical study published in *Lancet,* manual removal of head lice with a commercial combing kit was found to be less than half as effective as treatment with a prescription pediculicide. (Roberts RJ, et al. 2000.) In fact the 2006 Cochrane Systematic Review of head lice treatments (an independent, authoritative analysis of evidence-based research) states: "The results of the trial by Roberts et al (2000) indicate that physical control methods, such as combing/'BugBusting' are ineffective as a means of curing head lice infections. This type of method of intervention is very labeour intensive and requires a certain level of skill to be effective, which makes the treatment inappropriate as a primary treatment against head louse infestation." (Dodd CS. 2006) Indeed, Both the CDC and the American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over manual removal with special combs for the treatment of head lice. (Frankowski BL, et al. 2003; United States CDC Head Lice Fact Sheet, 2005.)

False Statements: The NPA attempts to convince consumers that using Lindane medications cause cancer. For example, they note: "[T]he U.S. EPA classifies lindane as a possible carcinogen" and that "Lindane should be handled as a **CARCINOGEN WITH EXTREME CAUTION.**" Similarly, the NPA states: "Case-controlled research shows a significant association between the incidences of brain tumors in children with the use of lindane-containing lice shampoos."

Facts: These statements are false. First, there have been no established links between the use of Lindane and the development of cancer, despite more than 50 years of clinical use on adults and children. This is supported, in part, by the results of an epidemiologic study published in 1997 involving more than 140,000 patients and up to 21 years of patient follow up, which concluded, "There is still no persuasive evidence from studies of humans that lindane, as ordinarily used clinically, is carcinogenic in humans."(Friedman GD. 1997)

Second, while it is true that Lindane was previously classified as a "possible/probable" carcinogen, in 2001 the EPA downgraded the carcinogenic potential of Lindane to the same low-level rating as other first-line scabies and lice medications, such as permethrin (Nix) and malathion (Ovide), concluding that, "[q]uantification of human cancer risk is not required." (United States EPA 2001) In 2004, the World Health Organization (WHO)

further concluded that, "In the absence of genotoxicity [ability to damage DNA] and on the basis of the weight of the evidence from the studies of carcinogenicity, JMPR [Joint Committee on Pesticide Residues] has concluded that lindane is not likely to pose a carcinogenic risk to humans." (WHO Drinking-Water Quality, 2004; United States EPA (Malathion) 2000; PAN Pesticides Database (Permethrin)).

Similarly, the NPA's statement regarding childhood brain cancer is also scientifically unsupported as determined by the FDA. In fact, the "case-controlled" research cited by the NPA (Davis et al. 1993) prompted a special review by the FDA's Dermatologic Advisory Committee the same year it was published, concluding that, "[T]here were several flaws in the data presented in the article and that there was an unlikely association based on the data. The committee voted that lindane was safe when properly used, and that is should remain on the market" (United States FDA, Lindane Assessment Memo, 2003) No change in the lindane prescription labeling was considered necessary.

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The false advertising claims and statements identified in this letter have and will continue to cause harm to Morton Grove. Morton Grove demands that the NPA issue a prompt and full retraction. Again, we also request that you promptly confirm in writing that you intend to comply with this demand for retraction and that you will provide a copy of the retraction and a list of the names and addresses of any individuals or entities that receive the retraction. As noted, we are prepared to provide you up to February 5, 2007 to prepare and issue this retraction. In the event the NPA ignores this request and refuse to issue the retraction, Morton Grove will pursue all available legal remedies.

Sincerely,

W. Gordon Dobie